

CLAIMS

1. A method of removing refractive defects formed in the matrix of a clear cyclic olefin component of a medical device during sterilization, said method comprising the following steps performed in sequence:

5 first heating said cyclic olefin component to a first temperature greater than 100°C in the presence of steam for at least 30 minutes to sterilize said cyclic olefin component; and

second maintaining the temperature of said cyclic olefin component at a second temperature of at least 80°C for at least 20 minutes to remove said refractive 10 defects from the matrix of said cyclic olefin component.

2. The method of removing refractive defects formed in the matrix of a clear cyclic olefin component as defined in Claim 1, wherein said method includes maintaining said cyclic olefin component at said second temperature in a dry 15 atmosphere relative to said first heating step.

3. The method of removing refractive defects in the matrix of a cyclic olefin component as defined in Claim 1, wherein said method includes heating said cyclic olefin component to said first temperature of greater than 100°C in the presence 20 of steam in an autoclave, then removing said cyclic olefin component from said autoclave and transferring said cyclic olefin component to an oven having a relatively dry atmosphere and maintaining said second temperature in said oven for at least 40 minutes.

4. The method of removing refractive defects in the matrix of a cyclic
olefin component as defined in Claim 1, wherein said method includes heating said
cyclic olefin component to said first temperature in an autoclave, then reducing the
temperature in said autoclave to said second temperature and maintaining said
5 temperature in said autoclave for at least 30 minutes.

5. The method of removing refractive defects in the matrix of a cyclic
olefin component as defined in Claim 1, wherein said component is a dry medical
container and said method includes heating said dry medical container in the presence
10 of steam in an autoclave, wherein said first temperature is between 120°C to 130°C to
sterilize said dry medical container, then reducing said temperature of said dry
medical component to said second temperature, wherein said second temperature is
between 80°C and 120°C.

15 6. The method of removing refractive defects in the matrix of a cyclic
olefin component as defined in Claim 1, wherein said component is a medical
container containing a liquid and said method includes heating said medical container
and liquid in the presence of steam in an autoclave for at least 30 minutes, wherein
said first temperature is between 120°C to 130°C, and then reducing the temperature
20 of said container and liquid to said second temperature, wherein said second
temperature is between 80°C and 100°C.

7. The method of removing refractive defects in the matrix of a cyclic
olefin component as defined in Claim 6, wherein said method includes maintaining

said medical container and liquid at said second temperature in a relatively dry atmosphere by discontinuing introduction of water into said autoclave.

8. The method of removing refractive defects in the matrix of a cyclic
5 olefin component as defined in Claim 1, wherein said component is a syringe barrel formed of a cyclic olefin polymer or copolymer, said method including sterilizing said cyclic olefin barrel in an autoclave at said first temperature, wherein said first temperature is between 120°C and 130°C, then reducing the temperature to said second temperature, wherein said second temperature is between 80°C and 120°C and
10 maintaining said second temperature.

9. The method of terminally sterilizing a syringe or cartridge assembly having a barrel formed of a cyclic olefin polymer, copolymer or blend containing a liquid, comprising the following steps performed in sequence:

15 filling said syringe or cartridge barrel with a liquid and sealing an open end of said barrel with a stopper;

heating said syringe or cartridge assembly in an autoclave in the presence of steam to a first temperature greater than 100°C, sterilizing said syringe or cartridge assembly; and

20 reducing the temperature of said syringe assembly to a second temperature of between 80°C and less than 100°C and maintaining said second temperature for at least 20 minutes, thereby removing refractive defects formed in the matrix of said syringe or cartridge barrel formed during sterilization.

10. The method of terminally sterilizing a syringe assembly as defined in
Claim 9, wherein said method includes heating said syringe assembly at said second
temperature in a dry atmosphere.

5 11. The method of terminally sterilizing a syringe assembly as defined in
Claim 10, wherein said method includes transferring said syringe assembly from said
autoclave to an oven having a relatively low humidity and maintaining said second
temperature of syringe assembly in said oven for at least 40 minutes.

10 12. The method of terminally sterilizing a syringe assembly as defined in
Claim 10, wherein said method includes reducing the humidity and temperature of
said syringe assembly in said autoclave to said second temperature and maintaining
said second temperature in said autoclave for at least 30 minutes.

15 13. The method of terminally sterilizing a syringe assembly as defined in
Claim 9, wherein said method includes heating said syringe assembly in said
autoclave to said first temperature, wherein said first temperature is between 120°C
and 130°C, then reducing the temperature of said syringe assembly to said second
temperature and maintaining said second temperature for at least 30 minutes in a dry
20 atmosphere.

14. A method of terminally sterilizing a medical container or delivery device formed of a clear cyclic olefin polymer or copolymer and removing refractive defects formed in the matrix of the cyclic olefin medical container formed during sterilization, comprising the following steps performed in sequence:

5 heating said cyclic olefin container or delivery device in an autoclave in the presence of steam to a first temperature greater than 120°C for at least 20 minutes, thereby sterilizing said cyclic olefin container or delivery device; and

reducing the humidity of said cyclic olefin container or delivery device and maintaining a second temperature less than 120°C and maintaining said cyclic
10 olefin container or delivery device at said second temperature at a reduced humidity for at least 20 minutes, thereby removing refractive defects formed in the matrix of they cyclic olefin container or delivery device during sterilization.

15. The method of terminally sterilizing a medical container or delivery device as defined in Claim 14, wherein said method includes maintaining said cyclic olefin container or delivery device at said second temperature in a dry atmosphere at said second temperature, wherein said second temperature is between 80°C and 120°C.

16. The method of terminally sterilizing a medical container or delivery device as defined in Claim 14, wherein said method includes removing said cyclic olefin container or delivery device from said autoclave and transferring said cyclic olefin container or delivery device to an oven having a relatively dry atmosphere and
5 maintaining said second temperature of said cyclic olefin container or delivery device in said oven, wherein said second temperature is between 80°C and 120°C for at least 40 minutes.

17. The method of terminally sterilizing a medical container or delivery device as defined in Claim 14, wherein said medical container contains a liquid and wherein said method includes reducing the temperature of said cyclic olefin container to said second temperature, wherein said second temperature is between 80°C and less than 100°C.
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15 18. The method of terminally sterilizing a medical container or delivery device as defined in Claim 14, wherein said method includes maintaining said cyclic olefin container in said autoclave and reducing the humidity and temperature to said second temperature in said autoclave.

19. The method of terminally sterilizing a medical container and delivery device as defined in Claim 14, wherein said medical container is a syringe barrel formed of a clear cyclic olefin polymer or copolymer and said method includes filling said syringe barrel with a liquid and sealing an open end of said syringe barrel with a
5 stopper forming a syringe assembly, then heating said syringe assembly in said autoclave to said first temperature, wherein said first temperature is between 120°C and 130°C, then reducing the temperature of said syringe assembly to said second temperature, wherein said second temperature is between 80°C and less than 100°C and maintaining said second temperature for at least 30 minutes.

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20. The method of terminally sterilizing a medical container or delivery device as defined in Claim 19, wherein said method includes maintaining said second temperature of said cyclic olefin container or delivery device at a relative humidity of less than 50 percent.

TRANSGENIC TECHNOLOGIES INC.